| AWARD NUMBER: | W81XWH-14-2-0141 |
|---------------------------|---|
| TITLE: | Development of Predictive Models of Injury for the Lower Extremity, Lumbar, and Thoracic Spine after discharge from Physical Rehabilitation |
| PRINCIPAL INVESTIGATOR: | MAJ Daniel Rhon |
| CONTRACTING ORGANIZATION: | The Geneva Foundation Tacoma, WA 98402 |
| REPORT DATE: | October 2017 |
| TYPE OF REPORT: | Annual |
| PREPARED FOR: | U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 |
| DISTRIBUTION STATEMENT: | Approved for Public Release; Distribution Unlimited |
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REPORT DOCUMENTATION PAGE

Form Approved OMB No. 0704-0188

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| 1. REPORT DATE | 2. REPORT TYPE | 3. DATES COVERED | | | |
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| October 2017 Annual | | 22Sep2016 - 21Sep2017 | | | |
| 4. TITLE AND SUBTITLE | | 5a. CONTRACT NUMBER | | | |
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| | Models of Injury for the Lower | 5b. GRANT NUMBER | | | |
| | racic Spine after discharge from | W81XWH-14-2-0141 | | | |
| Physical Rehabilitation | | | | | |
| | | 5c. PROGRAM ELEMENT NUMBER | | | |
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| 6. AUTHOR(S) | | 5d. PROJECT NUMBER | | | |
| MAJ Daniel Rhon | | 5e. TASK NUMBER | | | |
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| E-Mail: Daniel.i.rhon.mil@ma 7. PERFORMING ORGANIZATION NAME(| | 8. PERFORMING ORGANIZATION REPORT | | | |
| 7. PERFORMING ORGANIZATION NAME(S | S) AND ADDRESS(ES) | NUMBER | | | |
| The Geneva Foundation | | | | | |
| Tacoma, WA 98402 | | | | | |
| 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) | | 10. SPONSOR/MONITOR'S ACRONYM(S) | | | |
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| U.S. Army Medical Research | and Materiel Command | | | | |
| Fort Detrick, Maryland 21702-5012 | | 11. SPONSOR/MONITOR'S REPORT | | | |
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12. DISTRIBUTION / AVAILABILITY STATEMENT

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The objective and overall hypothesis is that service member performance on a battery of physical performance tests performed upon discharge from physical rehabilitation, will be able to predict 1) the risk of sustaining any injury as well as 2) the risk of reoccurrence of the same injury. A two-pronged injury prevention approach is required to optimize return to duty rates after injury: Screening for known preventable musculoskeletal risk factors and ensuring these risk factors are mitigated prior to discharge from rehabilitation. The current assumption is that a service member discharged from medical care is ready to return to full duty. Because history of prior injury is a well-established risk factor, every service member that is discharged from Physical Rehabilitation is already at a higher risk for future injury. Identifying those at increase risk of recurrence provides the ability for secondary and tertiary prevention programs to optimize return to duty rates. Hypothesis 1: Risk factors shown to be predictive of lower extremity and lumbar/thoracic spine injuries in other populations and in healthy service members will also be predictive of re-occurrence of original injury, future injury, and return to duty rates in service members being discharged from Physical Rehabilitation. Hypothesis 2: The injury prediction models will vary by age and sex. Hypothesis 3: A multi-factorial prediction model that accurately predicts risk of new and recurring injuries, as well as return to duty rates, will consist of multiple variables.

| 15. SUBJECT TERMS 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON USAMRMC |
|---|--------------|--------------|-------------------------------|------------------------|--|
| a. REPORT | b. ABSTRACT | c. THIS PAGE | | 8 | 19b. TELEPHONE NUMBER (include area code) |
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Table of Contents

| | <u>Page</u> |
|---|-------------|
| 1. Introduction | 4 |
| 2. Keywords | 4 |
| 3. Accomplishments | 4 |
| 4. Impact | 4 |
| 5. Changes/Problems | 5 |
| 6. Products | 5 |
| 7. Participants & Other Collaborating Organizations | 6 |
| 8. Special Reporting Requirements | 7 |
| 9. Appendices | 7 |

1. INTRODUCTION:

Musculoskeletal injuries have a significant deleterious effect on Soldier readiness. Screening algorithms for injury risk have been identified, but have not been evaluated in service members returning to duty after an injury. As past injury and pain with movement are strong risk factors for future injury, the ability to adequately screen service members for injury risk after they have been cleared to return to duty from an injury is of great importance. The purpose of this project is to determine if performance on a battery of functional tests after discharge from medical care, can predict risk for injury after returning to full duty following a spine or lower extremity injury.

2. KEYWORDS:

Injury prevention, injury prediction, injury risk, musculoskeletal, lower extremity, spine, return to duty

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Milestone 1: IRB approval and HRPO Approval (Initial Target – 6-8 months)

- STATUS – IRB approval at all sites with the primary site being approved on 26 February 2015 and the last sub-site approval on 25 February 2016

Milestone 2: Target recruitment met (Initial Target – 24 months)

- STATUS- 480 subjects enrolled (220 at WBAMC, 254 at WAMC, and 6 at BAMC). We were delayed by over a year hitting this goal.

Milestone 3: 1-year injury surveillance complete (Initial Target – 36 months)

- STATUS - Ongoing - over 150 subjects still need to complete their 1-year period of surveillance.

Milestone 4: Analysis for Primary Aims complete (42 months)

- STATUS - (not started)

What was accomplished under these goals?

The past year focused solely on recruitment and enrollment of subjects. We expanded to capture patients with musculoskeletal injuries in both primary care and specialty care (physical therapy) settings, that were discharged to return to full duty. The delays with IRB Approval due to IRBNet going away and adoption of eIRB put us about 10-12 months behind schedule. However, we did manage to complete enrollment of all 480 subjects during this last year and are in great position now to move into the injury surveillance phase, and finally the analysis phase.

What opportunities for training and professional development has the project provided?

Although our project was no intended to provide training and professional development, there have been several opportunities to do so. The MEDCOM Executive Health program implemented at BAMC utilized some of the screening components from this study, and our team provided the relevant training to healthcare providers on these injury screening procedures. MAJ Rhon and COL Teyhen are leading a session on injury prevention at the 4th International Congress on Soldier Physical Performance.

How were the results disseminated to communities of interest?

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?

As we just finished enrolling all of our subjects, this next year will entail following every subject through their 1-year period of surveillance. The final subject should complete their 1-year follow-up right at the end of the next reporting period. We will focus on maximizing compliance with follow-ups.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project? Nothing to Report

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

As the focus was on predicting return to duty after injury, we expanded our recruitment footprint to include musculoskeletal injuries in primary care.

Actual or anticipated problems or delays and actions or plans to resolve them

None

Changes that had a significant impact on expenditures

None

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

None

Significant changes in use or care of vertebrate animals. N/A

Significant changes in use of biohazards and/or select agents. N/A

6. PRODUCTS:

Publications, conference papers, and presentations

None

Journal publications.

Rhon DI, Teyhen DS, Shaffer SW, Goffar SL, Kiesel K, Plisky PP. Developing predictive models for return to work using the Military Power, Performance and Prevention (MP3) musculoskeletal injury risk algorithm: a study protocol for an injury risk assessment programme. Injury Prevention. 2016 Nov 24. pii: injuryprev-2016-042234. doi: 10.1136/injuryprev-2016-042234,

Acknowledgement of federal support: YES

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers, and presentations.

Nothing to Report

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

Nothing to Report

Inventions, patent applications, and/or licenses

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS What individuals have worked on the project?

| Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person on month worked: Writing IRB protocols for all 4 sites; Coordinating training at 2 main sites. Traveled to all 4 sites for site visits, coordinate with local IRBs, and help deliver training to research team. Continued oversight of all sites. Funding Support: N/A Name: Dr. Matt Hartshorne Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Dr. Danielle Langness Project Role: Researcher Identifier (e.g. ORCID ID): Name: Dr. Danielle Langness Project Role: Researcher Identifier (e.g. ORCID ID): Name: Dr. Danielle Langness Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Dr. Danielle Langness Project: Dr. Danielle Langness Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Dr. Danielle Langness Project: Dr. Danielle Langness Project Role: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Dr. Tina Greenlee Project: Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Dr. Tina Greenlee Researcher Identifier (e.g. ORCID ID): Nearest person month worked: Local assistance with IRB at WBAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site. In charge of enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary. Funding Support: 100% Local assistance with IRB at BAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site. In charge of enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary. Funding Support: 100% | Name: | MAJ Dan Rhon |
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| (e.g. ORCID ID): Nearest person month worked: Writing IRB protocols for all 4 sites; Coordinating training at 2 main sites. Traveled to all 4 sites for site visits, coordinate with local IRBs, and help deliver training to research team. Continued oversight of all sites. | Project Role: | |
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| Nearest person month worked: Local assistance with IRB at BAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site. Help with enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary. | Researcher Identifier | N/A |
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| | | planning local training meeting. Putting together study material for local site. Help with enrollment/recruitment at local site. Updating protocols and other |
| | Funding Support: | |
| | <u> </u> | |

| Name: | Dr. Rachel Mayhew |
|--|---|
| Project Role: | Research Physical Therapist |
| Researcher Identifier (e.g. ORCID ID): | N/A |
| Nearest person month worked: | 2 |
| Contribution to Project: | Local assistance with IRB at BAMC site. Assistance with setting up and planning local training meeting. Putting together study material for local site. In charge of enrollment/recruitment at local site. Updating protocols and other IRB documents as necessary. |
| Funding Support: | 100% |
| Name: | COL Deydre Teyhen |
| Project Role: | Associate Investigator |
| Researcher Identifier (e.g. ORCID ID): | N/A |
| Nearest person month worked: | 1 |
| Contribution to Project: | Consultation and input for planning, data collection, and follow-on steps after study. |
| Funding Support: | 100% |
| | |
| Name: | COL Scott Shaffer |
| Project Role: | Associate Investigator |
| Researcher Identifier (e.g. ORCID ID): | N/A |
| Nearest person month worked: | 1 |
| Contribution to Project: | Consultation and input for planning, data collection, and follow-on steps after study. |
| Funding Support: | 100% |

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Organization Name: University of Evansville Location of Organization: Evansville, IN Partner's contribution to the project

In-kind support: Contributed to the study design and provide consultation throughout the study enrollment process. Dr. Phil Plisky and Dr. Kyle Kiesel have an extensive history of this line of work with professional athletes. Some of the grant funds also went to help adapt the MP3 software for data collection pertinent to this particular study.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS:

9. APPENDICES: None

Development of Predictive Models of Injury for the Lower Extremity, Lumbar, and Thoracic Spine after Discharge from Physical Rehabilitation

ERMS# 13063063. Award # W81XWH-14-2-0141

PI: MAJ Daniel Rhon

Org: The Geneva Foundation Award \$1,084,186



Study/Product Aim(s)

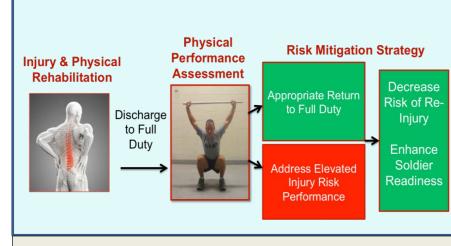
- •Aim 1: To improve prediction of injury-free, we will compare and contrast select performance test results in service members that sustain an injury versus those that do not during the 12-month follow-up period.
- •Aim 2: Develop predictive models from collected variables in order to derive a multi-factorial injury risk prediction algorithm.
- •Aim 3: Develop an optimal physical performance standard that should be met prior to discharge from physical rehabilitation with the aim of decreasing future injury risk and facilitating successful injury-free return to duty.

Approach

- Screen 480 Soldiers being discharged from physical rehabilitation
- Prospectively follow them for one year to identify injuries.
- Screening process includes movement and balance screens, measures of power, demographic data and biopsychosocial measures.
- Injury data will be collected through self-report, profile data, and healthcare utilization data. Clinical prediction rules will be used for algorithm development.

| digentim development. | | | | | | |
|--|--------|--------|--------|-------|----|----|
| Activities FY | 14 | 15 | 16 | 17 | 18 | 19 |
| IRB Approval, hiring and training of support personnel | | | | | | |
| Subject enrollment and data collection and 1-year follow-up. | | | | | | |
| Healthcare utilization pull from DoD database & medical records | | | | | | |
| Data analysis, interpretation, prediction model derivation, and reporting of results | | | | | | |
| Estimated Budget (\$1084K) | \$407K | \$380K | \$237K | \$60K | | |

Updated: 17 October 2017



Accomplishment: Enrollment goal has been met (480 subjects enrolled). We are now in the 1-year surveillance period.

Goals/Milestones

CY14 Goal – System Development/Demonstration

✓Optimal testing pathways established & tested

CY15 Goals - Data Collection

- ✓ IRB protocol submission/approval (submission only)
- ✓ HRPO Approval

CY16 Goal - Data Collection

- ✓ Initiate subject recruitment early 2016
- ✓ Collect follow up data regarding Injuries incurred for those enrolled

CY17 Goal – Data Collection (complete enrollment)

CY18 Goal - Data Collection (complete all 1-year follow-ups)

- ☐ Analyze data to determine greatest predictors of injury risk
- ☐ Develop prediction algorithms based on findings
- ☐ TMA approval for healthcare utilization data pull from PASBA CY19 Goal

☐ Risk mitigation strategies developed and linked to predictor variables

Comments/Challenges/Issues/Concerns

We were behind schedule to begin data collection in early 2016 due to delays in receiving USAMRAA approval to change sites and IRB Approval.

Budget Expenditure to date

Projected Expenditure: \$1084K Actual Expenditure: \$584K